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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,831	04/05/2001	Frederic Bevilacqua	2590-30	7748

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EXAMINER	
KIANNI, KAVEH C	
ART UNIT	**PAPER NUMBER**
2877	

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/806,831	Applicant(s) BEVILACQUA ET AL.
	Examiner Kevin C Kianni	Art Unit 2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 12-20* is/are rejected.

7)☒ Claim(s) *8-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Allowable Subject Matter

1. Claims 8-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

   (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5452723).

Regarding claim 1, Wu teaches a method for local and superficial characterization of a turbid medium (shown at least in fig. 1; see col. 2, lines 39) using the following parameters: 1) the refractive index n of the turbid medium (see col. 6, lines 62 and col. 7, lines 1-15), 2) the absorption coefficient μ_a of the turbid medium (col. 6, lines 59-60) 3) the reduced scattering coefficient μ_s of the turbid medium (col. 7, lines 1-8), 4) the phase function parameter $\lambda=(1-g_2)/(1-g_1)$ of the turbid media (see col. 6, lines 63-65 and col. 10, lines 15-45; wherein the phase function parameter λ can be indicated from equation 13 by $k(g')/k(g)=1-g'/1-g$ which can be written as $(1-g_2)/(1-g_1)$

and more in detail is described in col. 7, line 53-col. 10, line 46+); g_1, and g_2 are the first two moments of the Legendre polynomial development of the phase function p(see col. 8, lines 2-10 and col. 7, lines 36-42), comprising the steps of:

- measuring the spatially-resolved reflectance $R(\rho)$of the turbid medium (ρ being the source detector distance) by any means (see col. 7, lines 36-43 and col. 15, lines 13-17), comprising an illumination beam as a source and an optical detector, which, by using optional signal processing, which may involve filtering and deconvolution operation to correct for the non-zero area of either the illumination source or the detector, allows for the precise determination of the said spatially-resolved reflectance R(p),(see fig. 1, items 10, 16, 32, 29 and 30; see col. 4, lines 46-col. 5, line 14)-mathematically processing R(p) to compute at least one of the said parameters: n, μ_a, μ_s, y and/or the variations (see col. 10, lines 1-34), in time and/or space, of at least one of the said parameters: Δn, $\Delta\mu_a$, $\Delta\mu_s$, Δy, (col. 10, line 6) whereby an "Inverse problem", which consists in extracting the optical coefficients from the spatially resolved reflectance data is solved (see col. 12, equation 21b and col. 14, lines 1-21) , and whereby a "direct problem" consists in computing the spatially resolved reflectance from the values of the optical coefficients n, μ_a, μ_s, y involved in a model of propagation of the light in turbid medium (col. 9, lines 13-22) and whereby the said a model propagation incorporates a Legendre polynomial development to the second order of the said "phase function" (see col. 8, lines 2-10 and col. 9, lines 50-56), and whereby the said "phase parameter" y is introduced in the computation (col. 10, lines 20-46; wherein the phase function parameter y can be indicated from equation 13 by

k(g')/k(g)=1-g'/1-g which can be written as $(1-g_2)/(1-g_1)$ and more in detail is described in col. 7, line 53-col. 10, line 46+). However, Wu does not specifically teach wherein the above "phase parameter" y is introduced as an independent parameter. Nevertheless, Wu calculates the phase function parameters g in which k is a constant that depends on g (see col. 9, lines 1-21 and 65-6) and, as goal, a relationship between K(g) and g is found to define the reflection/phase function parameter in which the relationship is described in equation 13 consisting of k(g')/k(g)=1-g'/1-g=s. Thus, it would have been obvious to a person of ordinary skill in the art when the invention was made to modify Wu's formula 13 by expressing Wu's phase function expression k(g')/k(g)=1-g'/1-g, with an equal expression $(1-g_2)/(1-g_1)$= y, as independent parameter, since such a expression would provide a complete and uniform characterization of turbid medium to aid diagnosis (see col. 1, lines 42-46).

With regard to claim 2, Wu further teaches wherein said spatially resolved reflectance is measured by a probe comprising at least one optical fiber carrying the light from the source unit to the turbid medium and at least one optical fiber collecting the reflected light and carrying it to detection unit (see col. 3, lines 13-32), whereby the combination of a variety of emitting fibers and of receiving fibers yields a set of distances n at which the reflectance $R(\rho)$ is measured (see col. 7, lines 36-43 and col. 15, lines 13-17).

With regard to claim 3, Wu further teaches wherein said spatially resolved reflectance R(p) is measured for a set of values of p, by using a probe composed of optical fibers in any of the following configurations: one emitting optical fiber and a set of optical receiving fibers a set of optical emitting fibers and one optical receiving fiber a set of optical emitting fibers and a set of optical receiving fibers giving the spatially resolved reflectance R(p) at a variety of source-detector distances p (see fig. 1, items 26 and 28-332; also col. col. 3, lines 13-32 and col. 7, lines 36-44) and wherein the emitting and receiving fibers are arranged in one of the following configurations:
- on a line, - on crossed lines, - on a circle, - on an ellipse, - on crossed ellipses
- on a disk, a rectangle, or any surface, as a dense and contiguous arrangement of fibers, on any pattern resulting from the combination of the above mentioned patterns (see fig. 11-12, items emitting and receiving arrangement results; also col. 16, lines 35-48 and col. 17, lines 15-21).

With regard to claim 4, Wu further teaches wherein said spatially resolved reflectance is measured by an optical and electronic micro-system comprising a collimated or focused beam as illuminating source and ID or 2D arrays of optical detectors (see fig. 1 and 4, item 28, in which the 2D/3D micro-optic system 26 reflects and receive light; also col. 3, lines 13-32).

With regard to claim 5, Wu further teaches wherein either the probe or the optical and electronic micro-system are put in contact to the turbid medium (see fig. 1, item 28, in which the fiber optic probe(s) 28 is in contact to the turbid medium).

With regard to claim 6, Wu further teaches wherein said spatially resolved reflectance is measured by a non-contact system, comprising at least one of the following combination of optical systems: a fixed optical system to irradiate the turbid medium with a collimated or focused beam forming the illuminating source and a fixed optical system comprising an imaging system forming the image of the measured area of the turbid medium on a said "optical detector", which can be formed of ID or 2D array of optical detectors, whereby this second optical system can be identical to the first one and whereby the array of optical detectors can be either one of the following systems: a set of optical fibers, an optical and electronic micro-system (MOEM), a fixed optical system for the collimated beam illuminating source and a scanned optical system for the said "optical detector", a scanning optical system for the collimated beam illuminating source and a fixed optical system for the said "optical detector", a scanning optical system for the collimated or focused beam used as an illuminating source and a scanning optical system for the said "optical detector" (see at least fig. 1 and 4, item 28, in which the 2D/3D micro-optic system 26 reflects and receive light through fiber probes; also col. 3, lines 13-32)..

With regard to claim 7, Wu further teaches wherein the absorption coefficient ft, the reduced scattering coefficient tt,' and the phase function parameter y are determined by fitting the measured spatially-resolved reflectance $R(\rho, \mu_a, \mu_s, y)$ to a set of discretized data obtained by using Monte Carlo simulations , or to interpolating functions giving a continuous approximation of the discretized data obtained by Monte Carlo simulations (see col. 4, lines 3-26 and col. 16, lines 15-34), and whereby said "Monte Carlo simulations" are based on a photon propagation model comprising a phase function approximated by a Legendre polynomial development limited to the second order (col. 8, lines 1-11).

With regard to claim 12-17 , Wu further teaches wherein the illuminating source is a broadband source or a white light source and the detector unit comprises a spectrograph or any wavelength analysis system to measure the wavelength dependence of at least one of the parameters $R(n, \mu_a, \mu_s, y)$ (see fig. 1, items 16 and 30; also col. 9, line 21 and col. 10, lines 1-33); wherein said turbid medium is a biological medium (see abstract); wherein the measurement and processing is repeated at different locations of the sample, to build images of any one of the said parameters (n, μ_a, μ_s, y) (see fig. 12, scattering distances; also col. 9, line 21 and col. 10, lines 1-33); a source, a detection unit, reference means, signal processing means, a probe comprising at least one optical fiber connecting said source unit to the turbid medium and at least one optical fiber connecting the turbid medium to the said detection unit, and reference means b) where the distance between the source and the detector is

close to one transport mean free path (see fig. 1 and 4, items 12-32 and 45; also col. 7, lines 1-11); a) comprising an optical and electronic micro-system comprising at least one illuminating source, at least one detector, signal processing means and reference means, b) where the distance between the source and the detector is close to one transport mean free path (see fig. 1 and 4, items 12-32 and 45); a) comprising a collimated or focused beam used as an illuminating source, at least an optical detector for the detection unit, a fixed or scanning optical system for the illuminating source and a fixed or scanning optical system for the said "optical detector", signal processing means and reference means, b) where the distance between the source and the detector is close to one transport mean free path (see fig. 1 and 4, items 12-32 and 45; also col. 7, lines 1-11).

With regard to claim 18-19, Wu further teaches the distance between the collimated or focused optical beam used as illuminating source and the emitting point connected to an optical detector varies from 0. 1 to 2mm. for application to biological media and to turbid media having a transport mean free path similar to biological media (see col. 7, lines 1-11); the control of the homogeneity of the sample over the probed area is performed which can be carried out according to the following procedure: in the apparatus, disposing two illuminating fibers symmetrically in regard to the collecting fibers (see fig. 4, item fibers 40/46); comparing the reflectance curves for each illuminating fiber to detect the heterogeneity of the investigated region or obstructions beneath the fibers; and, if the two curves are sufficiently close, validating the

measurement and calculating the average of the two curves (see col. 21, line 50-col. 22, line 22 and lines 4234-67).

With regard to claim 20, Wu further teaches: 1) in order to perform relative intensity measurements, the differences of transmitted intensity between each fiber determined by performing a measurement on a turbid phantom illuminated uniformly or a diffusing sphere of perfectly uniform properties (see col. 25, lines 49-57);
2) in order to perform absolute intensity measurements, a calibration performed on a turbid medium of known optical properties (see col. 19, lines 60-67), which can be realized according to any one of the following recipes:
a) solid or liquid turbid medium which properties have been measured by other techniques, or reported in the literature (see col. 19, lines 60-67; wherein tissue is a liquid/solid turbid media measured at least according to equation 34),
b) water suspension of micro-spheres of known size distribution and refractive index (see col. 18, lines 433-65 and col. 19, lines 60-67).

Citation of Relevant Prior Art

4. Prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In accordance with MPEP 707.05 the following references are pertinent in rejection of this application since they provide substantially the same information disclosure as this patent does. These references are:

Tsuchiya 5517987

Jacques et al. 5353790

Tsuchiya 5441054

These references are cited herein to show the relevance of the apparatus/methods taught within this reference as prior art.

Contact Information

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaveh Cyrus Kianni whose telephone number is (703) 308-1216. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 6:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Font, can be reached at (703) 308-4881.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to:

(703) 308-7722, (for formal communications intended for entry)

or:

(703) 308-7721, (for informal or draft communications, please label "PROPOSED" or "DRAFT")

Hand delivered responses should be brought to Crystal Plaza 4, 2021 South Clark Place, Arlington, VA., Fourth Floor (Receptionist).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-0956.

Kevin Cyrus Kianni
Patent Examiner
Group Art Unit 2877

December 16, 2002

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